

**REMARKS**

Claims 1-18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,952,370 to Cummings, *et al.* ("Cummings") in view of U.S. Patent No. 6,572,819 B1 to Wu, *et al.* ("Wu").

In addition, double-patenting rejections have been entered against the pending claims in view of the claims in co-pending applications Ser. Nos. 09/941,925, 10/363,546 and 10/804,292.

Independent claims 1 and 11 have been amended to more clearly recited the present invention, and claims 12 has been amended to correct antecedent basis issues.

**1. The Claims Are Patentable Over Cummings.**

The Applicants respectfully traverse the rejection based on Cummings, on the grounds that this reference does not teach or suggest the features of the present invention for which it is cited, and its deficiencies are not cured by Wu.

The Present Invention: The present invention provides an apparatus and method in which objects are sterilized in a sterilizing chamber which enhances the performance of a novel, rapid approach to deposition and removal of a sterilizing vapor. Specifically, an aqueous hydrogen peroxide solution is abruptly expanded in a sterilization chamber which has wall surfaces which neither adsorb condensing vapor nor conduct any significant heat away from the chamber. The resulting over-saturation condition in the vapor, which causes nearly instantaneous formation of a condensate film on the surfaces of the objects to be sterilized, is enhanced by the recited chamber wall materials because the walls' resistance to adsorption and heat transfer maximizes the

amount of hydrogen peroxide which remains in the vapor phase and thus available to condense on the object's surface. The sterilization therefore proceeds more efficiently, the condensation of hydrogen peroxide not otherwise depleted by conventional chamber wall materials makes additional heat available in the liquid layer to help further disassociate the hydrogen peroxide and release an oxygen radical to attack any foreign bodies on the surfaces of the object.

The Cummings Reference: In contrast to the present invention, Cummings discloses essentially continuous hydrogen peroxide injection flow into a chamber whose surfaces must be maintained at specific temperatures in order to support sterilization.

Cummings teaches a relatively long sterilization process, which consequently introduces a number of complications to the process. In Cummings: (i) in order for a condensation film to form on the surfaces to be sterilized, the surfaces must be initially at a temperature below that of the incoming mixture of water vapor and hydrogen peroxide (*i.e.*, gradual condensation by absorption of heat from the vapor by the cold surface); (ii) additional hydrogen peroxide must be continuously injected into the sterilization chamber in order to maintain a sufficient concentration of hydrogen peroxide on the cold surface as the hydrogen peroxide both disassociates and evaporates in the presence of a water-removing vacuum; (iii) a water-removing vacuum must be carefully maintained *between* the evaporation point of water and the evaporation point of hydrogen peroxide; and (iv) the cold surface must be continuously cooled to ensure its temperature does not rise. Cummings at 2:41-

64 (“The vapor phase hydrogen peroxide is continued to be introduced into the chamber until the surfaces are sterile while preserving the temperature ranges of both the first [10°C] and second [20°C] portions of the surfaces.”); 3:47-54 (vacuum established to preferentially extract water); 3:55-60 (“injections of vapor phase hydrogen peroxide continue, thereby establishing a flow through the system”); 5:57-7:7 (full process description).

In addition to complicated steps to maintain the required environmental conditions, Cummings also disadvantageously requires considerable time to achieve the desired sterilization. *See, e.g.*, Cummings at 6:14-16 (initial vapor introduction “for approximately one minute”); 6:44-48 (subsequent additional hydrogen peroxide injections over 4 to 32 minutes).

Thus, Cummings discloses a cumbersome, time-consuming sterilization process requiring constant, careful parameter monitoring and maintenance. This reference, by relying on relatively slow condensation from a *sub-saturated* vapor, neither anticipates, nor provides any suggestion in the direction of, the present invention’s sterilization by *rapid generation* of an *over-saturated* vapor which immediately condenses on surfaces, without the need to carefully monitor or maintain surface temperatures or other environmental parameters such as the level of vacuum applied during drying.

Because Cummings neither discloses or suggests the present invention, including the present invention’s sterilization chamber with surfaces “made of poor heat-conducting, water-repellent material” in which “the vapor composite is rapidly expanded ... such that the vapor composite cools to below the hydrogen

peroxide dew point and condenses on all accessible surfaces of the objects to be sterilized ... followed by suctioning off after a pre-determined reaction time by further evacuation of the sterilization chamber,” the Cumming reference does not teach or suggest the present invention.

For its part, the Wu reference, which is directed to various arrangements of a rack which is placed in a sterilization chamber to hold objects to be sterilized, contains discussion of any sort regarding the materials from which the sterilization chamber’s wall surfaces should be form, let alone a suggestion to use poor-heat conducting, water-repelling materials in the present invention’s novel sudden-over-saturation, rapid condensation sterilization process. In view of the foregoing, the Applicants respectfully request the pending § 103(a) rejection be reconsidered and withdrawn.

**2. The Double Patenting Rejections Should Be Withdrawn.**

The Applicants respectfully traverse the pending provisional double patenting rejections of the claims over claims 1-20 of co-pending Application Ser. No. 09/941,925, claims 1-16 of co-pending Application Ser. No. 10/363,546 and claims 1-8 of co-pending Application Ser. No. 10/806,292, on the grounds that these claims are patentably distinct from the present invention.

Ser. No. 10/363,546: The present claims are directed to a process and apparatus in which an *over-saturated* vapor mixture is rapidly formed and immediately condenses on the surfaces of objects to be sterilized, this over-saturated mixture formation and condensation occurring in a sterilization chamber with walls which enhance the sterilization process by not depleting the

concentration of hydrogen peroxide available to heat the condensed liquid film.

The claims in co-pending Application Ser. No. 10/363,546 on the other hand, are directed to use of an under-saturated (i.e., superheated) vapor mixture, which is established in a chamber. This superheated mixture passes through a liquid-proof anti-bacterial barrier cover into a package, then condenses on a component. The sterilizing liquid film is then again put in a vapor state by evaporation to permit it to pass back out of the liquid-proof barrier cover and be withdrawn from the chamber.

The Applicants respectfully submit that this is not the “same inventive concept” as in the present invention’s over-saturation-based sterilization approach, *i.e.*, no claim in the present application could be literally infringed while literally infringing a claim in the corresponding application. Accordingly, consistent with the guidance in MPEP § 804, this pending provisional double-patenting rejection should be withdrawn.

Ser. No. 09/941,925: As noted above, the claims of the present invention are directed to the use of a low-heat conducting, non-adsorptive material for the structure of a sterilization chamber, in order to minimize depletion of the vapor volume so that the target objects in the chamber are more effectively sterilized. The Applicants respectfully submit that a *prima facie* showing of obviousness of either the present claims over the ‘925 claims, or the ‘925 claims over the present claims, sufficient to support the pending provisional obviousness-type double-patenting rejection, has not been made.

The 10/941,925 Application is entirely silent as to the material of its

sterilization chamber wall, and contains nothing which would suggest to one of ordinary skill that any particular wall material would be advantageous. While it is asserted in the October 21, 2004 Office Action that use of the claimed chamber materials is “intrinsic” to the present invention’s over-saturation condensation process (Office Action at 5), there is nothing in the applications which suggests, nor any explanation in the Office Action as to how, the claimed process “intrinsically” requires the use of such chamber materials.

Further, there is nothing in the cited art teaching or suggesting the use of low-heat conducting, non-adsorptive materials to avoid excessive hydrogen peroxide-depleting vapor condensation away from a target surface in a over-saturation condensation process. Alternatively considered, the ‘present Application teaches the use of a novel sterilization process which relies on the use of low-heat conducting, non-adsorptive chamber materials in order to ensure the sterilization process can be completed without condensation on the walls resulting in inadequate hydrogen peroxide concentrations at the surfaces of the objects to be sterilized. There is nothing in the present Application which teaches or suggests the use of the recited process without the recited special wall materials.

Accordingly, in the absence of any teaching or suggestion which renders either the present claims or the claims of the ‘925 Application obvious in view of one another, the threshold requirement for an obvious-type provisional double-patenting rejection have not been met, and this rejection should be withdrawn.

Ser. No. 10/806,292: As with '925 claims, the claims of the '292

Application are directed to a non-obvious variant of the present invention. As noted above, the present invention relies on rapid expansion of the hydrogen peroxide vapor to below its dew point in a specially-constructed sterilization chamber (one equipped with wall surfaces which enhance the effectiveness of the sterilization process) in order to generate an over-saturated mixture which then "flash" condenses on a target surface in a manner which suddenly heats the condensed liquid to release sterilizing oxygen radicals.

Because the present claims are directed to a process which does not rely on an external heat source to cause the hydrogen peroxide, there is no teaching or suggestion in the present application for the preheating of the target objects and/or the chamber as recited in the '292 Application claims. Conversely, the '292 Application teaches a sterilization process which requires preheating to ensure the sterilization process is completely effective. In view of this disclosure, nothing is to be found in the '292 Application to suggest the present claim's sterilization process without an external heat source.

In the absence of any teaching or suggestion which renders either the present claims or the claims of the '292 Application obvious in view of one another, this rejection should be withdrawn.

### CONCLUSION

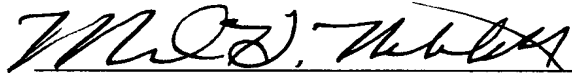
In view of the foregoing amendments, the Applicants respectfully submit that claims 1-18 are now in allowable form. Early and favorable consideration and issuance of a Notice of Allowance for these claims is respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029082/53055US).

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Respectfully submitted,



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